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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CLOW, LORI A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 02/24/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/766,450

Applicant(s)

COLLINS ET AL.

Examiner

Lori A. Clow, Ph.D.

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 and 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicants' arguments, filed 2 December 2002, have been fully considered but are not deemed persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-42 are currently pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

Art Unit: 1631

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-38 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over RepeatMasker™ software (RepeatMasker™ documentation: Smit and Green RepeatMasker™ at <http://ftp.genome.Washington.edu/RM/RepeatMasker.html>), first available in June 1997, in combination with Redasoft™(available September 15, 2000), and as evidenced by Butler (Bioinformatics: A Practical Guide to the Analysis of Genes and Proteins (1998), Baxevanis et al., Eds., John Wiley and Sons, Inc., pages 74-97).

Applicant claims that the RepeatMasker™ software does not teach or suggest using this software in combination with BLAST™. However, this is not deemed persuasive. As stated in the previous Office Action, the software screens DNA sequences for interspersed repeats and low complexity DNA sequences. The output of the program is a detailed annotation of the repeats that are present in the query (page 1, paragraph 1). Furthermore, the sequences can then be used in databases, such as BLAST™, in order to compare sequences and the data can be used to design primers or oligo probes (page 5, paragraph 4 and page 6, paragraph 6). As required by claims 2 and 19 genomic regions from mammalian sequences are used (including human) (page 3, paragraph 1). As required by claims 4 and 21 the software will output the sequences for each query (page 1, paragraph 5). It is clear that RepeatMasker™ is capable of performing these steps, as applicant had originally included the RepeatMasker™ software as a dependent claim that would perform step 1 of the said invention.

While the RepeatMasker™ software discloses steps of identifying repeat sequences and comparing sequences in a database to generate potential primers, it does not explicitly teach the primer design and ordering step. However, the Redasoft™ program does.

When combined with the software capabilities of Redasoft™, all limitations of said claims are met. Redasoft™ was the first to introduce web browser integration to the scientific software industry and to integrate online ordering of primers in the same program. The particular program utilized to design primer in this software scheme is Primer3, as required by claims 6, 7, 13, 14, 22, 23, 29, and 30. Furthermore the entire premise of this software is to allow users an environment in which they can design primers based upon sequences that were accessed from the web utilizing various unique parameters. The user is then able to directly place an order online within the same program (see description of the software on page 1). As with most primers that are generated, the intention is to produce an amplification product.

While not specifically designated as useful for FISH and CGH probes, it would have been prima facie obvious to one of ordinary skill in the art to use the methods in RepeatMasker™ and Redasoft™ to design FISH probes and CGH probes as required by claims 15-17 and 31-33, as the goal of the program is to design primers and probes. Further, it would have been obvious to combine the technology of RepeatMasker™ with the analysis and order tools available in the Redasoft™ program. The motivation to combine such bioinformatics software tools can be found in Butler (Bioinformatics: A Practical Guide to the Analysis of Genes and Proteins (1998), Baxevanis et al., Eds., John Wiley and Sons, Inc., pages 74-97).

Butler describes the user environment known as SeqLab which includes a comprehensive set of sequence analysis programs. SeqLab has the capability to be expanded to include

Art Unit: 1631

numerous publicly available databases and locally available programs, such that it is useful for a wide variety of bioinformatics tasks (see page 75). One of the main databases for use with this package is BLAST™. The appendix to this article lists several programs that are included initially in the package, including Prime, which selects primers for use in various reactions. Overall, the package was developed to deal with the need to combine several stand-alone packages so that users could interface a variety of programs in different combinations. Therefore, the motivation to combine Redasoft™ and RepeatMasker™ with Primer3 for the identification of sequences suitable for amplification of unique subregions and subsequent primer order would have been obvious to one of skill in the art at the time the invention was made, as such a suite of software was available for this task.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Art Unit: 1631

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703) 305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen
MARIANNE P. ALLEN
PRIMARY EXAMINER
GROUP 1800
AU 1631

February 21, 2003

Lori A. Clow, Ph.D.

Art Unit 1631

Lori A. Clow